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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,136	04/20/2001	Reid W. von Borstel	1331-337	2922

23117 7590 06/16/2004

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EXAMINER	
KRISHNAN, GANAPATHY	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/838,136	VON BORSTEL, REID W.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed February 26, 2004 has been received, entered into the record and carefully considered. The following information provided in the amendment affects the instant application:

1. Affirmation of the election of Group V, claims 41 and 42, for prosecution with the remaining claims in the case cancelled without prejudice

2. Remarks drawn to rejections under 35 U.S.C. 102

Claims 41-42 are pending.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5 and 31 of copending Application No. 09/930494('494 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Claim 41 is drawn to a method of reducing the side effects of a cancer chemotherapy agent by administering an effective amount of a pyrimidine nucleotide precursor wherein the chemotherapy agent is not a pyrimidine nucleoside analog, wherein the effective amount is 0.05 to 0.3g/Kg/day. Dependent claim 42 is drawn to specific side effects, namely peripheral neuropathy, chemotherapy-induced menopause, chemotherapy-associated fatigue and depressed appetite.

Claims 1 and 5 of the copending '494 application are drawn to a method treating pathophysiological consequences of mitochondrial dysfunction by administering an effective amount of a pyrimidine nucleotide precursor, wherein the dysfunction is caused by administration of a cytotoxic cancer chemotherapy agent. Dependent claim 31 of the copending '494 application recites peripheral-neuropathy as one of the pathophysiological consequence.

There is substantial overlap of the limitations in the instant and copending claims. Both are drawn to reducing side effects one of which is peripheral neuropathy. How the said disease or condition is caused is not of patentable import and does not patentably distinguish the instant claims over the claims of the copending '494 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of taxol induced neuropathy, does not reasonably provide enablement for the treatment of side effects induced by all other cancer chemotherapy agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims
(B) The state of the prior art
(C) The level of one of ordinary skill
(D) The level of predictability in the art
(E) The amount of direction provided by the inventor
(F) The existence of working examples
(G) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

Claims 41-42 are drawn to a method reducing side effects of cytotoxic cancer chemotherapy agents by administering an effective amount of a pyrimidine nucleotide precursor, wherein the cytotoxic chemotherapy agent is not a pyrimidine nucleoside analog. The breadth of the claims is seen to include the reduction of side effects of any cytotoxic chemotherapy agent that is not a pyrimidine nucleoside by administering an effective amount of any pyrimidine nucleoside precursor

The state of the prior art

The examiner notes that the prior art (The Merck Manual, 1987, 1221-1226) teaches several therapeutic agents that are not pyrimidine nucleoside analogs. These therapeutic agents display different types of toxicities, some of which are not common to all the agents.

The level of one of ordinary skill in the art

The level of one of ordinary skill in the art is an M.D./PhD in chemotherapeutics and administration.

The level of predictability in the art

The examiner acknowledges the probability and predictability that the instantly claimed pyrimidine nucleotide precursor would have a reasonable expectation of success. There is not seen sufficient data to substantiate the claim that any pyrimidine nucleotide precursor would reduce the side effects of any chemotherapy agent that is not a pyrimidine nucleoside analog. Because of the varied side effects of the chemotherapy agents the art is highly unpredictable. Not all side effects caused by a chemotherapy agent can be reduced with a single pyrimidine nucleotide precursor.

The amount of direction provided by the inventor

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the reduction of side effects of any chemotherapy agent that is not a pyrimidine nucleoside analog. The specification also fails to direct the

skilled artisan in correlative prior art procedures which might provide the basis using the said treatment.

The existence of working examples

The working examples set forth in the instant specification are drawn to the treatment of taxol-induced neuropathy, chemotherapy induced menopause, fatigue and depressed appetite by administration of triacetyluridine. One of ordinary skill in the art will not extrapolate this data provided using triacetyluridine alone to the reduction of side effects caused by any other agent.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be enabling for the said method of reducing the side effects of any chemotherapy agent that is not a pyrimidine nucleoside analog by administering an effective amount of a pyrimidine nucleotide precursor. One of ordinary skill in the art would have to carry out the process in order to determine the amount of the pyrimidine nucleotide precursor, the frequency of the dosage, etc. according to the type of side effect treated. This involves undue experimentation.

Claim Rejections - 35 USC § 102

The rejection of claims 41-42 under 35 USC 102(b) has been overcome by Applicants' arguments.

Conclusion

Claims 41-42 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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